REMARKS

Claims 57-82 are pending in the above-identified application, to which a Restriction Requirement under 35 U.S.C. §121 has been imposed as follows:

I. Claims 57-71, drawn to a pharmaceutical composition comprising a compound of Formula (I) and a compound having vitamin PP activity, selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va and Vb, classified in Class 514, Subclass 315...

II. Claims 72-81, drawn to a method of reducing side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity, classified in Class 514, Subclass 315...

III. Claim 82, drawn to a method according to Claim 73, wherein a further cancerostatic or immunosuppressive agent, different from compounds of Formula I is administered, classified in Class 514, Subclass 315...

In support of the Restriction Requirement, the Office Action alleges that Groups I and II/III are related as product and process of use, while Groups II and III are directed to related methods of reducing side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising the administration of a compound having vitamin PP activity. The Office Action has requested that applicants elect one group for continued examination herein. The Office Action has also alleged that the species of the compounds of Formula I and the specific compounds having vitamin PP activity contain patentability distinct species; the Office Action has requested applicants to elect one species from each category.

In order to be responsive to the Restriction Requirement, applicants elect, with traverse, the subject matter of Group I, Claims 57-71, drawn to a pharmaceutical composition comprising a compound of Formula I and a compound having vitamin PP activity, selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va and Vb.

Furthermore, applicants elect the species N-[-4-(1-benzoylpiperidin-4-yl)-butyl]-3-[pyridin-3-yl)-acrylamide. Moreover, applicants elect nicotinamide as the compound having vitamin PP activity.

Nevertheless, applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

However, applicants hereby traverse the Examiner's requirement for restriction and request reconsideration in view of the following Remarks.

Applicants respectfully request that this Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141-1.142. 35 U.S.C. §121 provides that the Commissioner may restrict an application when "two or more independent and distinct invention are claimed in a single application." (Emphasis added). Similarly, 37 C.F.R. §141(a) permits restriction conditioned upon a finding that independent and distinct inventions are found within one application. Only the statutory requirement that the various groups of claims are distinct has been proffered as the basis for the requirement of restriction. Even assuming, pro arguendo, that the Official Action was correct with respect to distinctiveness, there is absolutely no indication in the Official Action that Groups I, II and III are also independent.

In fact, applicant submits that Groups I, II and III are not independent.

MPEP §802.01 defines independent as follows:

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect.

Groups I, II and III are not independent. Group I relates to a pharmaceutical composition comprising a compound of Formula I in combination with a compound having

vitamin PP activity. Group II relates to the use of the compound having vitamin PP activity; it includes a combination of the compound having vitamin PP activity and a compound of Formula I. Group III relates to the use of the compound having vitamin PP activity and a compound of Formula I and a second cancerostatic or immnosuppressive agent added thereto. Thus, the subject matter of Groups I-III all contain a compound having vitamin PP activity. Moreover, except for Claim 72, all of the claims contain a compound having vitamin PP activity and a compound of Formula I. Thus, the subject matter of all of the claims are clearly is interrelated and interdependent, and are not "independent and distinct".

Thus, because these groups of claims are interdependent, and therefore not independent, the claims which the Office Action has grouped separately are not "independent and distinct" so as to justify the Restriction Requirement. It is therefore respectfully submitted that the Restriction Requirement is improper and cannot be maintained.

This Restriction Requirement is improper for another reason, it is not in compliance with MPEP §808.02. According to MPEP §808.02, where, "the classification is the same, the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions".

The Office Action has indicated that the classification of all three groups are the same; they all classified in class 514, subclass 315. Moreover, there is no indication provided of separate further classification and field of search. Further, the Office Action has not provided any separate status in the art of the various groups. Therefore, under these circumstances, in accordance with MPEP §808.02, the USPTO cannot impose a Restriction Requirement. Accordingly, the Restriction Requirement should be withdrawn.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In addition, the Courts have recognized the advantages to the public interest to permit patentees to claim all aspects of their invention, as the applicants have done herein, so as to encourage the patentees to make a more detailed disclosure of all aspects of their invention. The CCPA has observed:

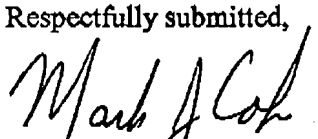
> We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects of what they regard as their invention, regardless of the number of statutory classes involved. (Emphasis added).

In re Kuehl, 456, F.2d 658, 666, 177 USPQ 250, (CCPA 1973).

Furthermore, applicants respectfully request that in view of increased Official Fees and the potential limitation of applicants' financial resources, a practice which arbitrarily imposes a Restriction Requirement may become prohibitive, and thereby contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

Hence, it is respectfully requested that the Examiner reconsider and withdraw the Restriction Requirement, and provide an action on the merits with respect to all of the claims.

Respectfully submitted,



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